## **Department of Legislative Services**

Maryland General Assembly 2011 Session

### FISCAL AND POLICY NOTE Revised

House Bill 3

(Delegate Valderrama)

Health and Government Operations

### Pharmacies - Taking Back and Disposing of Unused Drugs

This bill requires each pharmacy to take back and dispose of unused prescription and nonprescription drugs in accordance with guidelines established by the U.S. Food and Drug Administration (FDA).

## **Fiscal Summary**

**State Effect:** Special fund expenditures for the State Board of Pharmacy are unaffected. Potential minimal increase in general fund revenues due to the application of existing penalty provisions.

Local Effect: None.

**Small Business Effect:** Minimal.

#### Analysis

**Current Law:** A pharmacy permit is required of an individual in order to establish or operate a pharmacy in the State. A pharmacy located out of state that ships, mails, or delivers drugs or devices to Maryland residents must file for a nonresident pharmacy permit. If a pharmacy or nonresident pharmacy operates in violation of statute, the State Board of Pharmacy can suspend the pharmacy permit until compliance is met.

The board inspects pharmacies annually and upon opening and closing. Subject to hearing requirements, the board may seek disciplinary action against a pharmacist or pharmacy permit holder who violates any provision of the Maryland Pharmacy Act. A violator is subject to civil fines up to \$10,000. In addition, the board may seek

disciplinary action against a pharmacy technician who violates any provision under the Maryland Pharmacy Act. A violator is subject to civil penalties up to \$2,500.

Chapter 287 of 2006 established a prescription drug repository program regulated by the board. The program accepts donated prescription drugs for the purpose of dispensing them to needy patients in the State. However, prescription drugs can only be donated if they are in unopened, sealed, and tamper-evident unit dose packaging and have an expiration date at least 90 days from the date the drug is donated.

**Background:** Safe disposal of prescription drugs preserves patient safety, reduces abuse or unintended ingestion of prescription drugs, and limits the impact of unused medications on the environment. Many independent community pharmacies, including 34 in Maryland, participate in DisposeMyMeds.org, a website that directs consumers to local medication disposal programs. Sharps Compliance, Inc. offers the TakeAway<sup>TM</sup> Environmental Return System for unused consumer prescription drugs (excluding controlled substances) in which returned drugs are mailed to the company, processed by law enforcement officials, and destroyed. According to the board, 78 Maryland pharmacies participate in the program.

Under the federal Secure and Responsible Drug Disposal Act of 2010 (enacted in October 2010), individuals may now return lawfully obtained controlled substances for disposal. The U.S. Attorney General will issue regulations governing the transfer of controlled substances for disposal to prevent diversion.

FDA guidelines on proper disposal of prescription drugs state that consumers should:

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
- If no instructions are given, throw the drugs in the household trash, but first:
  - Take them out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter.
  - Put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag.

The SMARxT Disposal Campaign, a public-private partnership between the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America, was designed to encourage people to dispose of unused medication in their household trash, rather than flushing it down the toilet or pouring it down a sink or drain. Specific suggestions regarding medication disposal include sealing it in a plastic bag with other substances such as coffee grounds or sawdust to make it unappealing for animals or children to eat.

**Small Business Effect:** According to the board, 1,729 pharmacies hold permits, including 1,163 full service pharmacies in Maryland and 480 out-of-state mail-order pharmacies. It is unknown how many of these pharmacies are considered small businesses.

**Additional Comments:** Among other provisions, House Bill 1387 of 2010 would have required each pharmacy to develop a program for the disposal of unused prescription drugs that included the provision of a secure container into which the consumer could have deposited unused drugs for disposal by the pharmacy. The bill was heard by the House Health and Government Operations Committee but was subsequently withdrawn.

# **Additional Information**

Prior Introductions: None.

**Cross File:** SB 577 (Senators Muse and Benson) – Education, Health, and Environmental Affairs.

**Information Source(s):** Department of Health and Mental Hygiene, Department of Legislative Services

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